

EXHIBIT A

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4 UNITED STATES DISTRICT COURT
5 NORTHERN DISTRICT OF ILLINOIS
6 EASTERN DIVISION

7 NYCOMED GMBH, et al. Case No. 1:09-cv-04999
8 Plaintiffs Chicago, Illinois
9 November 23, 2009
10 v. Initial Status Conference
11 APOTEX INC., et al.,
12 Defendants.
13 -----

14 TRANSCRIPT OF INITIAL STATUS CONFERENCE
15 BEFORE THE HONORABLE VIRGINIA M. KENDALL
16 UNITED STATES DISTRICT JUDGE

17 APPEARANCES:

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09:01:24 1 (Commenced at 9:01 a.m.)

09:01:24 2 THE CLERK: 09C4999, Nycomed GmbH, et al. versus

09:01:30 3 Apotex Inc., et al.

09:01:39 4 MR. FELDMAN: Good morning, your Honor. Steve

09:01:40 5 Feldman and Sherrie Rollo and Jim White on behalf of Apotex.

09:01:44 6 THE COURT: Good morning.

09:01:44 7 MR. WHITE: Good morning, your Honor.

09:01:45 8 THE COURT: Good morning.

09:01:46 9 MR. O'MALLEY: Good morning. Joe O'Malley, Paul

09:01:48 10 Hastings, on behalf of the plaintiffs, Nycomed and Wyeth.

09:01:52 11 THE COURT: Good morning.

09:01:52 12 MR. O'MALLEY: With me is ...

09:01:53 13 MR. McELWAIN: Bill McElwain from Wilmer Hale also

09:01:56 14 for the plaintiff.

09:01:56 15 MS. FOSTER: Erica Foster.

09:01:58 16 THE COURT: Good morning.

09:01:58 17 MR. ASHKENAZI: Isaac Ashkenazi.

09:02:00 18 THE COURT: Good morning. Must be a patent case,

09:02:02 19 right?

09:02:02 20 (Laughter.)

09:02:03 21 THE COURT: Only my 21st, I think, for the docket.

09:02:07 22 Okay, folks. Tell me a bit about your case.

09:02:10 23 Plaintiffs first.

09:02:11 24 MR. O'MALLEY: Your Honor, this is a so-called

09:02:15 25 Hatch-Waxman Act patent case, and we're aware that you've had

09:02:19 1 them before.

09:02:19 2 This case involves our client's drug product
09:02:23 3 PROTONIX. It's a proton pump inhibitor. Treats acid reflux.
09:02:28 4 It's in the same class of drugs as Prilosec. You might have
09:02:30 5 seen the ads for Prilosec.

09:02:31 6 THE COURT: Right.

09:02:32 7 MR. O'MALLEY: Prior to the generic launch, this was
09:02:34 8 a \$2 billion a year drug product. As you're familiar with the
09:02:39 9 procedure in these ANDA cases, a generic who wants to copy the
09:02:43 10 drug files a so-called Abbreviated New Drug Application.

09:02:47 11 When they do that, they have to make a certification
09:02:52 12 with respect to each of the patents that the branded company
09:02:54 13 listed in the so-called Orange Book [sic].

09:02:56 14 With respect to this case, the patent at issue is the
09:03:01 15 so-called '579 patent, that is an active ingredient patent.
09:03:06 16 The active ingredient patent is always the crown jewel in the
09:03:10 17 patent portfolio of the branded company.

09:03:12 18 With respect to this '579 patent, about seven or
09:03:17 19 eight generics originally decided to respect the patent. They
09:03:21 20 filed a so-called paragraph 3 certification.

09:03:23 21 THE COURT: Right.

09:03:23 22 MR. O'MALLEY: Originally, defendant Apotex, decided
09:03:27 23 to respect the patent. They filed their ANDA, their
09:03:33 24 Abbreviated New Drug Application, in 2008, and at that time
09:03:35 25 they filed a paragraph 3 certification. Only a year later and

09:03:40 1 recently in July they changed that paragraph 3 to a paragraph
09:03:45 2 4 certification.

09:03:47 3 Now, as you may be aware from the materials that the
09:03:50 4 parties submitted, this patent has been litigated on behalf of
09:03:56 5 the plaintiffs and three generics who challenged it in the
09:04:00 6 District of New Jersey now for five years. Originally the
09:04:02 7 case started in 2004. It's now three consolidated cases
09:04:07 8 against three generics.

09:04:09 9 That case is going to go trial sometime in the first
09:04:14 10 quarter of 2010. We don't have a trial date. The parties
09:04:18 11 have a deadline to submit dates that they're available in the
09:04:21 12 first quarter. We've done that. We've recommended a date in
09:04:26 13 January with a backup date sometime in early March or the end
09:04:29 14 of February. The other parties have not yet submitted their
09:04:33 15 letters with trial dates.

09:04:36 16 It's our belief, your Honor, that that litigation
09:04:40 17 will control the fates of all the generics who have filed
09:04:44 18 ANDA. And the way that works, your Honor, if you're not
09:04:48 19 familiar with it, is let's assume that in that Jersey action,
09:04:53 20 the '579 patent is invalidated in a way that collaterally
09:04:57 21 estops us.

09:04:59 22 If that happens, all the generics who did not
09:05:02 23 challenge it will then convert their so-called paragraph 3 to
09:05:05 24 a paragraph 4, and then shortly thereafter the FDA will
09:05:11 25 approve those generics and they could go on the market.

09:05:15 1 We, plaintiffs, are not really sure why Apotex, one,
09:05:20 2 waited after filing their ANDA, but then more fundamentally,
09:05:25 3 why have they challenged it now? Because it's very hard to
09:05:29 4 see any scenario by which you can grant them any meaningful
09:05:35 5 relief.

09:05:36 6 And what I mean by that, your Honor, is if you do not
09:05:40 7 issue a judgment of invalidity of the patent before July 19th
09:05:45 8 of 2010, then the plaintiff cannot get any relief. Their ANDA
09:05:52 9 will not be approved until the pediatric exclusivity that's
09:05:57 10 associated with this patent expires some six months after July
09:06:02 11 2010. And after that the patent is expired and there is no
09:06:05 12 relief to be had.

09:06:07 13 So that's really the source of our suggestion that we
09:06:12 14 stay the case. We're going to give defendants all the
09:06:15 15 discovery we have from that case, all the documents,
09:06:18 16 transcripts, and so on. But then our suggestion is stay the
09:06:22 17 case until we see what happens in Jersey. And then likely,
09:06:29 18 again, there's going to be no time that you can do anything
09:06:34 19 meaningful. If the patent's invalidated, again, in a manner
09:06:39 20 that collaterally estops us, that's the end of this case.

09:06:42 21 If, on the other hand, we get a judgment that the
09:06:45 22 patent's valid, then as a practical matter likely that will
09:06:49 23 decide the fate of all the parties from that point forward.
09:06:53 24 So that's, from our perspective, where we are, your Honor.

09:06:58 25 THE COURT: Okay. Who wants to speak?

09:06:59 1 MR. FELDMAN: I will speak, your Honor.

09:07:00 2 THE COURT: There's questions pending, and he's

09:07:02 3 thrown a few out for you.

09:07:04 4 MR. FELDMAN: Absolutely.

09:07:05 5 Our position is this is an invalid patent. The

09:07:08 6 fellow circuit has already denied them a preliminary

09:07:11 7 injunction in the New Jersey case finding that there's a

09:07:13 8 substantial likelihood that the defendants would, in fact, be

09:07:15 9 able to prove that it was invalid.

09:07:17 10 That case is going to a jury trial, I believe, as he

09:07:20 11 said, anywhere between January and March.

09:07:22 12 Our position is that we would like our day in court.

09:07:27 13 We would like to go to trial prior to the expiration of this

09:07:29 14 patent, so that we will not be restricted by this pediatric

09:07:33 15 exclusivity. What you're talking about is six months of

09:07:36 16 exclusivity. He says it's a \$2 billion a year drug. You can

09:07:39 17 do the math. You're talking about close to a billion dollars'

09:07:42 18 worth of sales for them, if they can block everybody on

09:07:45 19 pediatric exclusivity. The Hatch-Waxman Act was not designed

09:07:50 20 to give them those sorts of boondoggles.

09:07:52 21 It's designed so that the generics can get their

09:07:55 22 products to market as quickly as possible and the public can

09:07:57 23 benefit from that.

09:07:58 24 So our position is, is we will take their discovery

09:08:01 25 from the other case. We'll do whatever cleanup discovery we

09:08:04 1 need to do. We'll do limited expert stuff and basically get
09:08:06 2 our case ready for trial so that we could go to trial at the
09:08:09 3 end of May or beginning of June, if, in fact, that's
09:08:11 4 necessary. If, as he says, it's obviated by the other trial,
09:08:16 5 for example, if the patent's invalid there, then we don't have
09:08:18 6 to go to trial. We won't have to do all this.

09:08:19 7 But, frankly, we're entitled to our day in court.
09:08:22 8 We're not collaterally estopped by that case because we're not
09:08:25 9 part of it and that's what we would like, your Honor.

09:08:26 10 THE COURT: Well, you've seen our new standardized
09:08:28 11 patent rules, right?

09:08:30 12 MR. FELDMAN: Yes, your Honor.

09:08:30 13 THE COURT: Which I worked on with the committee.

09:08:32 14 MR. FELDMAN: Right.

09:08:34 15 THE COURT: And we certainly don't have a trial date
09:08:37 16 within six months of the filing of a suit. So how do you
09:08:40 17 propose that we're going to get through all of the issues plus
09:08:44 18 my ruling on any proposed summary judgment issues before
09:08:51 19 July 15th?

09:08:51 20 MR. FELDMAN: Well, as you know, your Honor, there's
09:08:55 21 an opt-out provision of -- under the local rules for good
09:08:57 22 cause and I think there is good cause here.

09:08:59 23 Again, a lot of the discovery has already been done
09:09:02 24 in the other case. There's not going to be a lot of issues as
09:09:02 25 far as that goes, and we're pretty ready to take on their

09:09:05 1 discovery and look at it and see if there's any cleanup stuff
09:09:07 2 that we need to do.

09:09:08 3 We can propose -- we have, in fact, proposed to them
09:09:10 4 a fairly expedited schedule, which I think is still realistic,
09:09:16 5 you know. The real deciding factor here, though, is you, your
09:09:18 6 Honor, in whether you're willing to give us a trial date in
09:09:22 7 time for you to actually decide the case.

09:09:23 8 THE COURT: Well, and that also includes the fact
09:09:25 9 that I have two monster civil trials scheduled for over a
09:09:30 10 year, one of which begins in March and is an eight-week trial.
09:09:35 11 That's the Paine case, which is a 1983 cause of action,
09:09:40 12 beginning March 13.

09:09:42 13 And it's followed by an Exxon Mobile case, which we
09:09:49 14 anticipate will be another six weeks, which, I believe, is in
09:09:53 15 May.

09:09:54 16 So let me just get those dates. Paine is scheduled
09:09:57 17 to begin -- it's Paine versus City of Chicago, 06-3173, is
09:10:02 18 scheduled to begin March 13th, and go all the way through
09:10:07 19 April 23rd.

09:10:09 20 There is another trial beginning on the 26th of April
09:10:15 21 and another different trial, May 3rd, and then the Exxon
09:10:20 22 Mobile case begins May 10th and is expected to go through to
09:10:25 23 June 4th, and then I'm out June 14 and 21.

09:10:34 24 So I don't know. Let's see. Maybe there's three
09:10:37 25 days -- July 7th, 8th, and 9th -- that are open right now. So

09:10:41 1 we're going to do a three-day trial on your Hatch-Waxman Act
09:10:46 2 case after where are the summary judgments and how are we
09:10:49 3 getting all this done and why did you file so late?

09:10:53 4 MR. FELDMAN: Your Honor, the reason we filed so late
09:10:55 5 is because as the Federal Circuit already found, there's
09:10:59 6 substantial likelihood ...

09:10:59 7 THE COURT: It did what?

09:11:00 8 MR. FELDMAN: The Federal Circuit already found that
09:11:01 9 there's a substantial likelihood that this patent is invalid.
09:11:06 10 We believe it's invalid, having --

09:11:06 11 THE COURT: Did they just do that?

09:11:08 12 MR. FELDMAN: They did it within the last -- we filed
09:11:10 13 shortly after that. That's ...

09:11:14 14 THE COURT: Okay. Any response?

09:11:16 15 MR. O'MALLEY: Yes, your Honor.

09:11:17 16 First of all, the preliminary injunction decision at
09:11:21 17 the District Court level was in July, the summer, I believe,
09:11:26 18 of 2007. So it was prior to them ever filing their ANDA.

09:11:33 19 Now -- and in that District Court opinion, the judge
09:11:36 20 never finds that the patent is likely invalid, nor did the
09:11:40 21 CAFC --

09:11:41 22 THE COURT: The Federal Circuit's decision was in
09:11:43 23 July, did you say?

09:11:44 24 MR. O'MALLEY: The District Court decision.

09:11:46 25 THE COURT: Oh, the District Court.

09:11:47 1 MR. O'MALLEY: It was in summer of 2007. The CAFC
09:11:49 2 decision was -- I don't have that available to me.

09:11:56 3 But in both decisions the Court found only that there
09:12:00 4 was a substantial question as to the bely of the patent. The
09:12:05 5 Federal Circuit just found there was no abuse of discretion
09:12:07 6 and, indeed, found that the District Court had committed error
09:12:10 7 with respect to at least one of its factual findings. So it
09:12:16 8 wasn't that strong.

09:12:16 9 On this point that we're holding up generic
09:12:20 10 competition, that simply isn't true, your Honor. Two generics
09:12:23 11 have launched. The product is already generic. And with
09:12:28 12 respect to those two generics in the District of New Jersey,
09:12:32 13 that's going to be a jury trial, and we have a claim for
09:12:34 14 damages, which will be decided at some point in the future,
09:12:36 15 assuming the patent is upheld, as most active ingredient
09:12:41 16 patents are.

09:12:43 17 MR. FELDMAN: Your Honor, I can give you the cite to
09:12:45 18 the Federal Circuit opinion --

09:12:46 19 THE COURT: Okay.

09:12:46 20 MR. FELDMAN: It is 566 F.3d 999. It's a 2009
09:12:51 21 decision.

09:12:52 22 THE COURT: 566 F.3d what?

09:12:54 23 MR. FELDMAN: 999.

09:12:56 24 THE COURT: 999.

09:12:57 25 MR. O'MALLEY: If I may, one further point on this

09:13:00 1 notion that we have a realistic schedule, we don't see it,
09:13:06 2 your Honor. The day that they have proposed to file
09:13:09 3 dispositive motions is April 26, 2010. And then they proposed
09:13:15 4 the end of May for the trial, which obviously given your own
09:13:19 5 schedule is never going to work. But, I mean, even assuming
09:13:24 6 one could do a three-day trial July 7, 8, 9, then you have a
09:13:29 7 week to issue a bench trial [sic] on a complicated active
09:13:34 8 ingredient patent.

09:13:36 9 In the District of New Jersey there are literally
09:13:40 10 dozens of expert witnesses that potentially are going to
09:13:43 11 appear at trial.

09:13:46 12 THE COURT: Well, I can't give you a ruling on this
09:13:49 13 today, because this is quite a conflict. You're on polar
09:13:55 14 opposites and, you know, certainly if it's a situation that is
09:13:59 15 deserving of being placed on an expedited schedule, which, by
09:14:03 16 the way, there's no motion requesting such a thing.

09:14:07 17 I mean, the case was filed August 19th, and this is
09:14:09 18 the first, you know, common joint status issue that I have
09:14:12 19 read when I got the report. I was surprised there was no
09:14:15 20 expedited motion or any request to move the case along more
09:14:20 21 quickly.

09:14:21 22 So I don't know whether if I do think that it can
09:14:25 23 move along more quickly, based upon the allegations in the
09:14:29 24 complaint, whether I have an obligation to see if there's
09:14:31 25 another Court that can handle it with the trial schedule that

09:14:34 1 is not as booked as mine. I need to look into these issues,
09:14:39 2 and I'll have to do that over the course of the next week.

09:14:43 3 So I will see all of you again -- let's see. This is
09:14:47 4 the holiday week. I'll see you on December 7th at 9:00 a.m.
09:15:00 5 and let you know how we're going to proceed and if we're going
09:15:04 6 to work with any type of schedule that preserves this
09:15:08 7 July 15th end game. And I'll look up the Federal Circuit
09:15:14 8 opinion and see what is there. I thought there were two
09:15:19 9 opinions, someone mentioned to me another opinion.

09:15:22 10 MR. O'MALLEY: Yeah. There was a District Court
09:15:24 11 opinion.

09:15:24 12 THE COURT: Okay.

09:15:25 13 MR. O'MALLEY: I don't know if it was --

09:15:26 14 THE COURT: That's from --

09:15:27 15 MR. FELDMAN: Your Honor, it's actually -- if you'll
09:15:30 16 look at docket 29 that we filed. In the joint status report,
09:15:33 17 all of these are in there.

09:15:34 18 But the cite to the District Court opinion is
09:15:38 19 532 F.Supp.2d 666.

09:15:42 20 THE COURT: How ironic, 666 and 999?

09:15:46 21 Okay. All right, folks. Let me take a look at it
09:15:49 22 and see what I can do. I'm actually sitting on the Seventh
09:15:56 23 Circuit on the -- I mean, the Federal Circuit on the 8th and
09:15:59 24 the 9th. Am I actually in that date or do I fly to D.C.?

09:16:04 25 THE CLERK: 12/7, you're leaving on 12/7.

09:16:08 1 THE COURT: Okay. I think -- but we have a call that
09:16:10 2 morning, right?

09:16:11 3 Okay. So I'll see you before I head to the Federal
09:16:14 4 Circuit. I'll ask them, right? All right. Thank you very
09:16:17 5 much.

6 (Concluded at 9:16 a.m.)
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13 C E R T I F I C A T E
14
15 I certify that the foregoing is a correct transcript from
16 the record of proceedings in the above-entitled matter.
17
18 /s/April M. Metzler, RPR, CRR, FCRR November 23, 2009
19 April M. Metzler, RPR, CRR, FCRR Date
20 Official Federal Court Reporter
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